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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,991	03/28/2001	Maurice Zauderer	1821.0050004	9763

26111 7590 03/25/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
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WASHINGTON, DC 20005

EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/818,991

Applicant(s)

Zauderer

Examiner  
Padmeshri Ponnaluri

Art Unit  
1639



*Restriction purposes only*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-137 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-137 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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**DETAILED ACTION**

1. Claims 1-137 are currently pending in this application.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner at [andrew.wang@uspto.gov](mailto:andrew.wang@uspto.gov) or 7(703)306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10 and 22-88, drawn to a method of selecting a target polynucleotide, comprising introducing a library of insert polynucleotides into a population of host cells, and the insert polynucleotides has target polynucleotide which promotes cell death, classified in class 435, subclass 6.

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- II. Claims 11-20, drawn to a method of selecting a target polynucleotide (as in claim 1, and differs from claim method by exposing the target polynucleotides to an agent, classified in class 435, subclass 6.
- III. Claim 21, drawn to a method of selecting a target polynucleotide (as in claim 1, but differs by reciting that the expression of target polynucleotide effects several different cellular process which are different from 'cell death' in claim 1 method), classified in class 435, subclass 6.
- IV. Claims 89-109, drawn to a method of constructing library of insert polynucleotides, classified in class 435, subclass 69.1.
- V. Claims 110-113, drawn to a method of selecting a target polynucleotide comprising introducing a library of insert polynucleotides in to a population of host cells, and expression of target polynucleotide inhibits the cell death, classified in class 435, subclass 6.
- VI. Claims 114-117, drawn to a method of selecting a target polynucleotide comprising introducing a library of insert polynucleotides in to a population of host cells, and exposure of host cell to an agent promotes cell death and expression of target polynucleotide inhibits the cell death, and collecting polynucleotides from host cells which do not undergo cell death, classified in class 435, subclass 6.

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- VII. Claims 118-126, drawn to a method of selecting a target polynucleotide comprising introducing a library of insert polynucleotides in to a population of host cells, and expression of target polynucleotide alters the phenotype of host cell, classified in class 435, subclass 6.
- VIII. Claims 127-137, drawn to a method of selecting a target polynucleotide encoding a secreted product comprising dividing host cell comprising a library of insert polynucleotides, and expression of target polynucleotide alters the phenotype of indicator cell, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-VIII are all drawn to patentably distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The different method group inventions are distinct and are not capable of use together and have different method steps. Thus restriction between the groups is proper.

4. Inventions of group I and group II are related as process of making a product ( library of insert polynucleotides) and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not novel (library of insert polynucleotide), restriction is proper between said method of making the product and method of using.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undue search burden, and restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicants are requested to elect single species for each of the following:

- a) a single species of cellular effect from claim 5;
- b) a single species of host cell from claim 6;
- c) a single species of solid support from claim 8;
- d) a single species of support structure from claim 9;
- e) a single species of insert polynucleotides from claim 10;
- f) a single species of target polynucleotide;
- g) a single species of suicide gene or gene product;
- h) a single species of promoter from claims 45 or 51;
- I) a single species of host cell;

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- j) a single species of eukaryotic virus vector from claim 71;
- k) if applicants elect 'pox virus vector' as eukaryotic virus vector, applicants are further requested to elect a single species of pox virus vector from claims 73-75;
- l) a single species of promoter from claims 86 or 87;
- m) a single species of linear DNA virus genome from claims 99-102;
- n) a single species of helper virus;
- o) a single species of transfer plasmid promoter in claim 109;
- p) a single species of reporter gene product in claim 123;
- q) a single species of agent;
- r) a single species of indicator cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

8. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri  
Patent Examiner  
Technology Center 1600  
Art Unit 1639  
21 January 2003

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: **P. Ponnaluri**

ART UNIT: **1639**

SERIAL NUMBER: 09/818,991

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY  
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: \_\_\_\_\_  
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\_\_\_\_\_

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